

4240-118

Section II (Remarks)**Amendment of the Claims**

Claims 1, 3, 6 and 7 have been amended herein to overcome the objection to claim 7, as well as the rejection of claims 1-7 under 35 USC 112.

In claim 1, the term "derivative" has been deleted from the recital, so that sub-paragraph (a) of claim 1 now recites:

"(a) dissolving an acid-soluble chitosan in organic acid, or dissolving a water-soluble chitosan in water, to prepare a chitosan solution,"

thereby making it clear that the chitosan recited in the claim is either an acid-soluble chitosan or a water-soluble chitosan.

Such revision of claim 1 is fully consistent with and supported by the original disclosure of the application. See, for example, the specification at page 2, lines 15-17, referring to "acid-soluble chitosan" and "water-soluble chitosan."

Corresponding amendments have been made in claims 3 and 7.

Claim 7 has been objected to for inclusion of the symbol "~" and claims 3, 6 and 7 have been rejected under 35 USC 112, second paragraph as indefinite, for the use of such symbol.

In response, claims 3, 6 and 7 have been amended to delete such symbol, in favor of the phrase "from _ to _" now set forth in such claims.

Claims 1-7 are therefore now in fully proper form and compliance with 35 USC 112, second paragraph.

Patentable Distinction of Claimed Method over Cho et al. Korean 2001000706 A

4240-118

In the January 11, 2007 Office Action, claims 1-7 were rejected as unpatentable under 35 USC 103 (a) over Cho et al. Korean 2001000706 A.

Such rejection is traversed, and reconsideration the patentability of claims 1-7, as amended, is requested in light of the remarks set out below.

The salient teachings of Cho et al. Korean 2001000706 A are set out at page 3, lines 6-14 of the present application:

“Furthermore, methods for producing chitosan salt are known, in which chitosan dissolved in organic acid is mixed with salt solution, and the mixture is subjected to stirring, evaporating, drying and crystallizing steps (Korean patent publication KR 01/00706A and KR 01/103538A). However, KR 01/103538A has no mention of the blood pressure lowering efficacy of the chitosan salt. KR 01/00706A suggests the blood pressure lowering efficacy of the chitosan salt, but has a problem that it requires the recrystallizing step so that production process is complex and a great increase in production costs is caused upon the mass production of the chitosan salt.” (Emphasis added)

and such teachings of Cho et al. Korean 2001000706 A are comparatively evaluated against the method of the present invention in Example 5 at page 9, line 18 to page 10, lines 17 of the present application:

“Example 5: Economic efficiency of inventive method for producing chitosan-containing salt

In a method for producing chitosan-containing salt according to the prior art, chitosan, lactic acid and natural sea salt are mixed with each other to prepare a mixture solution. The mixture solution is dried by evaporation, and then subjected to grinding, screening and packaging steps. In contrast to this, in the producing method of the present invention, an aqueous solution of chitosan and lactic acid is coated on or bound to granular natural sea salt by spraying, and then subjected to screening and packaging steps. Thus, the inventive method for chitosan-containing salt requires no tank facilities for the preparation of the mixture solution and enables the recrystallizing and grinding steps to be eliminated (see FIG. 6).

4240-118

Energy costs required for the mass production of the chitosan-containing salt were compared between the prior art (Korean patent publication 01/00706A) and the inventive method. As shown in Table 2, energy cost required to produce 300 kg of chitosan-containing salt by the prior art (KR 01/00706) was about 33,175 won in Korean currency.

Table 2: Comparison of energy costs required in producing 300 kg of chitosan-containing salt according to prior art method and inventive method

Contents	Prior art method	This inventive method
Raw materials	(chitosan + lactic acid) solution 1000L (chitosan 3wt%, lactic acid 1.5wt%) + natural sea salt 270kg	(chitosan + lactic acid) solution 100L (chitosan 10wt%, lactic acid 5wt%) + granulated natural sea salt 290kg
Amount of water to be evaporated	955L	85L
Consuming heat capacity	$955L \times 597.5(\text{enthalpy of water at } 0^{\circ}\text{C}) = 570,612.5\text{kcal}$	$85L \times 597.5(\text{enthalpy of water at } 0^{\circ}\text{C}) = 50,787.5\text{kcal}$
Consuming electric energy	$570,612.5\text{kcal} + 860\text{kcal/kw} = 663.5\text{kw}$	$50,787.5\text{kcal} + 860\text{kcal/kw} = 59.1\text{kw}$
Energy cost	$663.5\text{kw} \times 50\text{won/kw} = 33,175\text{won}$	$59.1\text{kw} \times 50\text{won/kw} = 2,955\text{won}$

Meanwhile, according to the inventive method, 100 liter of aqueous solution containing 10% chitosan and 5% lactic acid was prepared, coated on or bound to 290 kg of granular natural sea salt by spraying, and then subjected to drying and screening steps. In which case, the amount of water to be evaporated was 85 liters, and a heat capacity of 50,787.5 kcal was consumed, which indicates an electric energy of 59.1 kw. Thus, energy cost in producing 300 kg of the chitosan-containing salt according to the inventive method was 2,995 won in Korean currency, which is at least 11 times lower than that of the prior art."

4240-118

Thus, in a direct comparison with the method of Cho et al. Korean 2001000706 A, the method of the present claimed invention achieved a 91% reduction in the amount of water required to be evaporated, a 91% reduction in heat consumption, a 91% reduction in electric energy consumption, and a 91% reduction in energy cost, as compared with such method of Cho et al.

The present invention as claimed therefore achieves a major advance over the prior art methodology of the cited reference. As set out in Example 5 above, "the inventive method for chitosan-containing salt requires no tank facilities for the preparation of the mixture solution and enables the recrystallizing and grinding steps [required by Cho et al. Korean 2001000706 A] to be eliminated."

The Cho et al. Korean 2001000706 A reference expressly teaches to mix chitosan into a salt solution with stirring, evaporation, drying and (re)crystallization steps being required to yield the chitosan salt. There is no derivative basis in such Cho et al. Korean 2001000706 A reference for applicants' presently claimed invention.

Further, as stated at page 3, lines 18-22 of the specification of the present application:

"The present inventors have conducted many researches to solve the above-mentioned problems occurring in the prior art [of the required recrystallizing step and complex and costly character of the approaches of the prior art including Cho et al. Korean 2001000706 A], and consequently, found that when a solution of chitosan is sprayed on salt particles to bind the chitosan to the salt particles, chitosan-containing salt having a blood pressure lowering function can be economically produced without performing a recrystallization process. On the basis of this discovery, the present invention was perfected."

The foregoing is highly probative evidence of the non-obviousness of the present invention, particularly since the inventors for the instant application include a number of individuals who were inventors of the prior art method of Cho et al. Korean 2001000706 A, and who as such prior art method inventors were uniquely knowledgeable of such technology. Despite such expertise in the ranks of the present inventors, the present inventors "conducted many researches to solve the above-mentioned problems occurring in the prior art" before making the discovery of the present invention (page 3, lines 18-23 of the specification).

4240-118

Despite this compelling evidence of the non-obviousness of the present claimed invention, the January 11, 2007 Office Action cites Cho et al. in making the following assertions on page 4 of that Action:

- “it is obvious to use any means or common technique to react or interact said chitosan and salt especially since said common means or technique does not alter the chitosan-containing salt composition formed”
- “[I]t would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method of Cho et al. to prepare a chitosan-containing salt (a salt having chitosan) for lowering blood pressure and for and antibiosis [sic], and to use any common means or common technique to react or interact said chitosan with said salt especially since said means or technique does not alter the chitosan-containing salt composition formed”
- “[O]ne having ordinary skill in the art would have been motivated, to use the method of Cho et al. to prepare a chitosan-containing salt (a salt having chitosan) for lowering blood pressure and for and antibiosis [sic], and to use any common means or common technique to react or interact said chitosan and salt, based on factors such as availability and/or need, and especially since said means or technique does not alter the chitosan-containing salt composition formed.”

The rejection therefore is premised on the citation of a single reference, Cho et al., which fails to disclose or suggest the presently claimed method. Despite this failure of the reference to provide any derivative basis for the presently claimed method, “any common means or common technique to react or interact said chitosan and salt” are hypothesized as the basis for the obviousness rejection of applicants’ claims. No “common means or common technique” are identified, nor is any additional source of knowledge or information, or any further reference cited.

It simply is hypothesized that one would review Cho et al. and thereupon discard the specific sequence of process steps expressly taught in such reference, and somehow use “common means or common technique” to arrive at the applicants’ claimed invention.

The requirements for rejection of claims under 35 USC 103 are set forth in MPEP 2143, and include the requirement identified in MPEP 2143.03 that there be specific teaching or suggestion in the prior art of the claimed subject matter:

2143.03 All Claim Limitations Must Be Taught or Suggested

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

-MPEP 2143.03

4240-118

Here, there is simply a general assertion that “any common means or common technique” would be used by those skilled in the art to yield the present invention. This assertion, apart from simply being speculative, without any identification of how, or from what source, one skilled in the art would actually proceed from Cho et al. to the applicants' claimed invention¹, improperly ignores the fact that Cho et al.'s process contacts the chitosan and salt in a saturated liquid medium, and discloses no alternative to such technique.

Further, the factual evidence of the making of the invention by persons who included a number of the inventors of the prior art process of Cho et al. only after “many researches to solve the... problems occurring in the prior art [of Cho et al.]” (page 3, lines 18-23 of the specification) constitutes *prima facie* evidence of the non-obviousness of the presently claimed invention.

For all of these reasons, it is requested that the rejection of claims 1-7 based on Cho et al. be withdrawn, in recognition of the non-obvious and patentable character of such claims.

¹ In this regard, it is noted that there must be a specified and persuasive basis for the rejection. See *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection).

4240-118

RECEIVED
CENTRAL FAX CENTER
MAY 11 2007

CONCLUSION

The applicants' pending claims 1-7 are patently distinguished over the art, and in form and condition for allowance. The examiner is respectfully requested to responsively issue a Notice of Allowance.

The time for responding to the January 11, 2007 Office Action without extension was set at three months, or April 11, 2007. Applicants hereby request a one (1) month extension of time under 37 C.F.R. § 1.136 to extend the deadline for response to and including May 11, 2007. Payment of the extension fee of \$60.00 specified in 37 C.F.R. § 1.17(a)(1), as applicable to small entity, is authorized by the enclosed Credit Card Payment Form PTO-2038. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that this application can be passed to issue at an early date.

Respectfully submitted,

Date: May 11, 2007

/steven j. hultquist/
Steven J. Hultquist
Reg. No. 28,021
Attorney for Applicants

Date: May 11, 2007

/kelly k. reynolds/
Kelly K. Reynolds
Reg. No. 51,154
Attorney for Applicants

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 4240-118

Encl.
Credit Card Payment Form PTO-2038 [1 page]

The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284